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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,950	10/06/2003	Marcel Hunn	33635/US	3584

7590 08/21/2007  
David E. Bruhn  
Dorsey & Whitney LLP  
Intellectual Property Department  
50 South Sixth Street, Suite 1500  
Minneapolis, MN 55402-1498

EXAMINER
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MACNEILL, ELIZABETH

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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08/21/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/679,950

Applicant(s)

HUNN ET AL.

Examiner

Elizabeth R. MacNeill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3,5,8-15,17-21,28-34 and 36-56 is/are pending in the application.
- 4a) Of the above claim(s) 9,12,15,17,18,28-32,34,36 and 38-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,5,8,10,11,13,14,19-21,33,37 and 53-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Species I in the reply filed on 2 May 2006 is acknowledged. The traversal is on the ground(s) that all the claims read on the elected species. This is not found persuasive because in the description of figures 1a and 1b of Species I, it is specified that the outer material of the cannula is dissolved after application and is of a greater hardness than the inner material. Additionally, no reference to a curved or bent cannula is given.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 3,5,8,10,13,14,21,53, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Bley et al (US 5,762,630).

Bley teaches a cannula (117 and 113) composed a first material (shape memory polymer such as MM-3510, Col 4 at line 50) which is thermally susceptible, and a second material (hub 117).

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 33, 37, 55, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwatschenko (US #4,306,563) in view of Bader et al (US 4,835,248).

Regarding claims 33, Iwatschenko teaches "A cannula that increases in pliability during use, wherein the cannula comprises a water-absorbing material (8) of a first variable hardness that decreases in hardness upon water absorption (Col 3 line 8) and a material having a second hardness (plastic)

Iwatschenko does not disclose that the material of a polyamide.

Bader et al discloses a polyamide based coating which dissolves in the body and can be used for catheters (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a polyamide coating with the variable hardness catheter of Iwatschenko since "these polymers are metabolized into nontoxic, nonallergenic and nonimmunogenic compounds and are excreted." (Col 1 line 61-64)

Regarding claim 37, the water-absorbing material is the outer material of the cannula, and the material having the second hardness is the inner material of the cannula. As to claims 55 and 56, the tip would be capable of piercing the skin or a septum. Additionally, the hardness of a steel needle is dependent on the shape and size of the needle.

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3. Claims 3,5,8,10,11,13,14,91-21,53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwatschenko (US #4,306,563) in view of Bley (US 5,762,630)

Regarding claim 8, Iwatschenko teaches "A cannula (2) which increases in pliability during application, wherein, prior to application, said cannula comprises one a material of a first variable hardness (8) and a second material having a second hardness (2), of which said material having the greater hardness is at least partially dissolved during use." See Col 3 lines 20-25 and Claim 1.

Iwatschenko does not disclose that the material is thermally susceptible.

Bley discloses thermally susceptible polymer which dissolves in the body and can be used for catheters (Col 4 line 50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a thermal coating with the variable hardness catheter of Iwatschenko since such a coating would rapidly soften in the body.

Regarding claim 3, the two materials are a composite (Fig 1)

Regarding claim 5, the composite is a solid-state material (plastic, Col 1 line 9) and an organic polymer (PVA, Col 3 line 10)

Regarding claim 10, the cannula contains a material of lower hardness (2) than the dissolving material (8)

Regarding claim 11, the material of first variable hardness at least partially surrounds the material having a lower initial hardness (Fig 1)

Regarding claim 13, the hardness of the material of lower hardness does not change during use (plastic, Col 1 line 9)

Regarding claim 14, the material of greater hardness surrounds the material of lower hardness (Fig 1)

Regarding claim 19, the PVA is readily water soluble, and meets the limitation of the applicants specification regarding the preferred materials as disclosed in the specification.

Regarding claim 20, the material having the greater hardness is removed during use (by dissolution)

Regarding claim 21, the materials are separated by layers (Fig 1)

### ***Response to Arguments***

Applicant's arguments filed 7 August 2007 relating to claims 33 and 37 have been fully considered but they are not persuasive. Iwatschenko discloses that his polymer is water absorbing explicitly at Col 2 line 21, "In the simplest case such a coating may be soluble in water."

### ***Conclusion***

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

